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09/889,901

07/24/2001

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05/12/2008

EXAMINER

MENON, KRISHNAN S

ART UNIT

PAPER NUMBER

1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 09/889,901 | Applicant(s) YEN ET AL. | |
| | Examiner Krishnan S. Menon | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 58-79 are pending as amended 4/15/08 in the RCE of 6/5/07. Claims 58 and 72 are independent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A) Claims 76-78 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-48 of copending Application No. 10/704,468; and the pending claims of Application 09/890,290. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are for a product with same limitations as in the claims of application '468.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

B) Claims 58-79 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. 6,663,745 and US 6,582,496. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patents recite all the limitations claimed in the instant claims.

C) Claims 57-79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 10/489,214. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '214 application recite all the limitations of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

1. Claims 76-78 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0 299 459 A2.

EP teaches an all perfluorinated thermoplastic hollow fiber membrane cartridge as in instant claims (see fig 5, page 4 lines 35-40, page 5 lines 36-49). Re method of

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making the cartridge, these claims are product by process, and “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re *Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Even though the reference teaches other thermoplastic materials as useful for making the cartridge (like polyethylene), the preferred material is all thermoplastic fluoropolymer (page 2 lines 32-39, page 4 lines 35-40, page 5 lines 43-48, working examples).

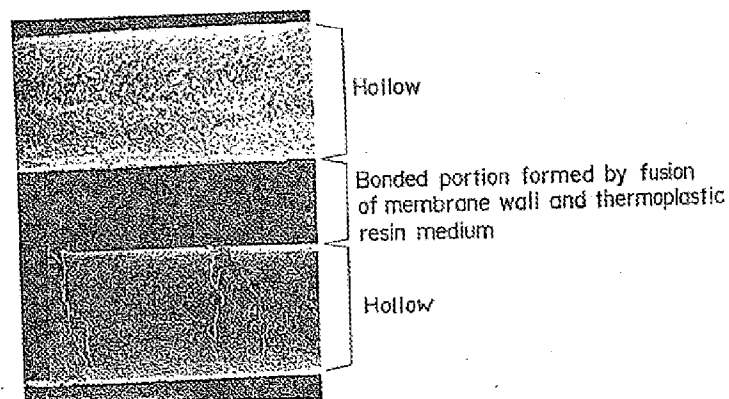
The hollow fibers are taught as with or without having an inorganic filler (see page 7 lines 9-12 and page 8 lines 27-28), and such fillers, if present, are completely extracted out leaving only thermoplastic fluoropolymer in the cartridge. EP’459 also teaches potting material as same or different from the material of the hollow fiber in page 7 line 25 – page 8 line 16. With regard to the melt temperature of the potting material, since this the melt temperature is for the purpose of making the hollow fiber bundle, and does not otherwise be a structural limitation, this limitation does not make the claim patentable. EP’459 also covers this limitation in the range of the softening point in page 7 lines 30-35.

Regarding the newly added limitation on 4/15/08:

whereby complete encapsulation and sealing of the fibers by the potting resin takes place without damage to the fibers or collapse of the hollow fiber membrane lumen.

Complete sealing is essential in the potting of hollow fibers, and this happens in all the references, and without which the cartridges would leak. There is complete sealing and no fiber damage and collapse in the teaching of the reference, as is seen in the SEM picture of the potted fiber ends reproduced below:

FIG. 6



2. Claims 76-78 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 USC 103(a) as being obvious over, JP 4-354521.

JP teaches an all perfluorinated thermoplastic hollow fiber membrane cartridge as in instant claims (see abstract, figures, and paragraph 18 and 19). Materials for the membrane are any fluoro-resin including PTFE. Materials for the housing are PTFE, PFA, FEP, etc., and material for the sealant resin are PFA or FEP (preferred). No inorganic fillers are mentioned. Limitations on the method of making the cartridge are not patentable: these claims are product by process, in re Thorpe. Complete sealing is

essential in the potting of hollow fibers, and this happens in all the references, and without which the cartridges would leak.

Claim Rejections - 35 USC § 103

3. Claims 58-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yagihashi et al (US 5,885,454), EP 0 299 459 A2, JP'521, Huang et al (US 5,284,584), **AND/OR** Muto et al (US 5,066,397).

Yagihashi teaches a method of forming a hollow fiber bundle by putting in parallel layers of thermoplastic hollow fibers over one or more strips of potting material, and winding the array in order to form the bundle, and then melting the potting strip to form the seal as claimed. (See abstract, col 4 lines 33-62, and figures 4A-F and 5).

Yagihashi teaches a variety of thermoplastic polymers and the corresponding potting strip in col 10 line 65 – col 11 line 8, but is not specific about the fluoropolymers.

EP teaches such fluoropolymers and potting material that has a melting point below the melting point of the fiber material as claimed – see page 5 lines 36-48, page 4 lines 35-40; example 5 for all perfluorinated thermoplastic. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of EP in the teaching of Yagihashi to have the membrane cartridge for high temperature applications with low TOC in the filtrate as taught by EP (abstract and page 2).

JP also teaches an all fluorinated resin cartridge as shown in paragraph 2 above. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of JP in the teaching of Yagihashi because JP teaches that the all fluorinated

resin construction would be advantageous for high temperature and chemical resistance (abstract).

Yagihashi also teaches the method as being for making fiber bundles with high packing density (col 3 lines 31-44), but does not specifically state the actual packing density as 45-65%. However, this would be inherent in the process since the applicant's process is the same, and the desired value for the packing density could be optimized based on the bundle-side flow, process fluids, and the cartridge flux requirements. Discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980); In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Huang teaches a method of making a hollow fiber cartridge by making a bundle by laying parallel hollow fiber layers and laying a strip of the potting material in the molten form, the hollow fibers and the potting material all thermoplastics, and the melting point of the potting material being at least 5C below the melting point of the fiber material, and mounting the potted bundle in a housing and attaching the end-caps as claimed – see abstract, figures and col 4 lines 10-35. Melt index 100g/10 min – see col 4 lines 25-35, forming the potted bundle, **cooling and then reheating the bundle** – see column 14 lines 40-55. However, Huang does not appear to teach specifically

thermoplastic fluoropolymers, even though fluoropolymers are included in the list of polymers for the potting resins (see column 11, lines 33-48).

Muto also teaches an all-thermoplastic fluoropolymer hollow fiber cartridge as claimed, with the process of making (see abstract, figures, column 4, lines 36-45 and column 6, lines 10-33).

See KSR Int'l. v. Teleflex Inc., 127 S. Ct. 1727, 1732, 82 USPQ2d 1385, 1390 (2007). "it is commonsense that familiar items have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle". "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." Therefore, it would be obvious to one of ordinary skill in the art at the time of invention to combine the above references to arrive at the claimed invention.

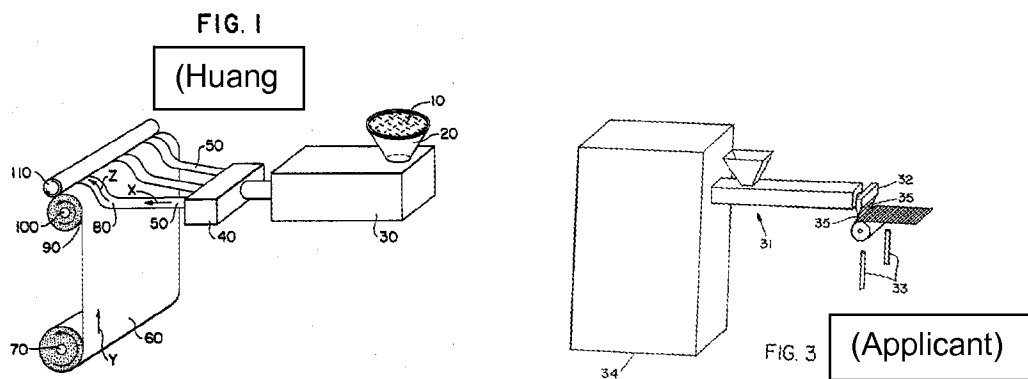
Teachings of Huang or Yagihashi appear to be differing from the claimed invention in the specific material being selected for the cartridge, thermoplastic fluoropolymer. However, this is not a patentable invention over the prior arts because such use of thermoplastic fluoropolymer is well known and used by several references, exemplified by Muto, and the EP and the JP references. They all teach that the thermoplastic fluoropolymer is good for chemical and high temperature stability, and for very low extractables. This motivation had been discussed several times during the prosecution of this application.

Applicant, in the arguments submitted with this RCE on 6/5/07, contents that the references do not teach a second heating step. The examiner respectfully disagrees

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with this argument. Huang teaches in column 14, lines 40-55 that adequate flow of the resin into the fabric should be assured to prevent any gaps or voids, and that an alternate procedure would be to allow the molten resin band to solidify as it is extruded on to the hollow fiber fabric, and then reheat to melt and form the tube sheet. Thus the reference teaches removing voids and also cooling and re-heating as claimed.

Particularly, applicant's disclosed process appears to be identical to that of Huang, as seen in the figures reproduced below:



Huang teaches in column 14, lines 50-55:

"... following extrusion, the molten band of resin can be allowed to solidify, and subsequently can be re-heated by any suitable means restoring it to a molten state while retaining its desired shape, and then directed onto the fabric to produce a tube sheet."

Thus the reference teaches that following the extrusion of the molten resin (first heating step) on to the membrane fabric, it is allowed to solidify (cooling), and then reheated (second heating step) by a suitable means while retaining its desired shape [spirally wound] to direct the molten resin into the [hollow fiber] fabric. Applicant applies

the molten resin on to the fabric as shown in figure 3, and then reheats at a later stage as in figure 5 to finish the potting.

Response to Arguments

Applicant's arguments filed 4/15/08 have been fully considered but they are not persuasive.

With respect to the double-patenting rejections, complete encapsulation and sealing of the fibers by the potting compound is necessary and take place in all the references because without a complete seal, the hollow fiber cartridges would leak and would not work. Applicant has not proven that such a problem exist in the teachings of the reference with any convincing evidence.

With respect to Muto, the reference teaches filling the ends of the hollow fibers with gypsum before making the fusion bond for potting, which assures no fiber collapse due to fusion bonding. See column 7, lines 20-56. Thus, structurally, there is no difference between the teaching of Muto and applicant's claimed product.

The argument that fiber walls remain distinct from the potting material and the materials are thus physically different in applicant's design is not convincing because (1) applicant uses fusion bonding - the potting material is fused before applying on the hollow fibers. The examiner submits that the fused potting material (which is the same as the fiber wall material) would diffuse into the pores of the hollow fibers, this making the fiber wall and the potting indistinct.

Argument regarding the Huang process is purely speculative.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Krishnan S Menon/
Primary Examiner, Art Unit 1797